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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,350	10/01/2003	Ursula Schindler	02481.1655-01	3812
22852	7590	07/28/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			PATEL, SUDHAKER B	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/674,350

Applicant(s)

SCHINDLER ET AL.

Examiner

Sudhaker B. Patel, D.Sc.Tech.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/497,723.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. <u>7/23/04</u> .                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/1/03</u> .   | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

Applicants' communication paper dated 7/7/04 is acknowledged. Applicants have cancelled claims 1-10, and presented claims 11-34.

Applicants' arguments and remarks have been considered, and found persuasive for the withdrawal of the Double Patenting rejections made in the earlier Office Communicated paper dated 4/9/04. Therefore, these DP rejections are now withdrawn.

The claims 11-34 as now presented are definite and have clarity. Therefore, the rejections made under 35 U.S.C. 112 paragraph second, and one, are now withdrawn.

After further review, and reconsideration, this application is found not ready for the allowance in, as is condition for the reasons stated bellow. See also, enclosed interview summary dated 7/23/04.

### ***Drawings***

There is a confusion arising out of the status as appearing in the Bibliographic data for this file. It states that there are 42 sheets/Drawings in this case. Examiner will initiate to correct the BIB data. However, applicants are also urged to take necessary action for correcting this situation. The examiner regrets inconvenience.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 11-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 has a structure for Formula I, which does not represent exactly and definitely the compounds as claimed herein. Applicants' novel compounds have partially hydrogenated quinazoline core, whereas the instant claim 11 represents a saturated 5-membered ring, which is fused to 1,3-diazine core. Correction to 6-membered saturated ring fused to 1,3-diazine core is required.

***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on 10/1/03 is being considered by the examiner. Signed copy of PTO Form 1449 is enclosed with this communication for applicants' records.

***Conclusion***

***Allowable Subject Matter***

4. Claims 11-34 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph and other matter/rejections, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

5. The closest prior art(s) of record ref. Schindler et al (WO2000046214) does not designate US and therefore it does not qualify for rejection(s) under 35 U.S.C.102(e).

6. Following prior art(s) are related to instant invention, but differ from the claimed subject matter in the following manner. See parent case, U. S. Application Sr. # 09497723, filed 2/4/2000:

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- a. Lee et al (J. Med. Chem. 38/18, 3547-57(1995)) teaches compounds with a core: "2-Phenyl-N-phenylmethyl)-4-quinazolineamine", which is fully unsaturated, whereas the instant claims have hydrogenated quinazoline core
- b. Lee et al (EP 579496) teaches compounds with a core: "2-imidazole-4-NH-CH<sub>2</sub>Phenyl/Cyclohexane-hydrogenated quinazoline", wherein the 2-position is not an aryl or phenyl as claimed herein.
- c. Murata et al (EP 826673) teaches compounds with a core: "2-Pyrrolidinecarboxamide, N,N,dialkyl or N alkyl, N phenyl-2-phenyl-4-hydrogenated quinazoline", wherein unlike instant compounds, 2-phenyl is unsubstituted, and the 4-pyrrolidine is substituted by 2- position with – COOH. Applicants' invention requires substituted phenyl group at 2-position of hydrogenated quinazoline.
- d. The other closest prior art ref. of record Chen (U.S.P. 4306065) teaches making of compounds with a core: " 4-piperidinol or 3-pyrrolidinol, 1-(2-phenyl-4-quinazolinyl)-" wherein the quinazoline is unsaturated and phenyl is unsubstituted as well.

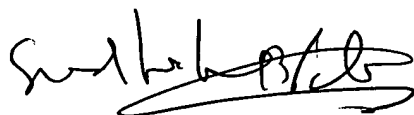
The above references either alone or in combined form do not indicate or suggest to arriving at the instant compounds.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is (571) 272-0671. The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on (571) 272 0674 or Sr. Examiner Mr. Richard Raymond at (571) 272 0673 or Mr. James O. Wilson at (571) 272-0661. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sudhaker B. Patel, D.Sc. Tech.  
July 23, 2004.



RICHARD L. RAYMOND  
MUKUND J. SHAH  
SUPERVISOR  
EXAMINER  
ART UNIT 1624  
ART UNIT 1624/1623